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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/758,683

01/14/2004

Jeannette Whitcomb

11068-078-999

4994

7590  
JONES DAY  
222 East 41st Street  
New York, NY 10017

03/12/2007

EXAMINER

PARKIN, JEFFREY S

ART UNIT

PAPER NUMBER

1648

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/12/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/758,683

Applicant(s)

WHITCOMB, JEANNETTE

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 December, 2006, and 05 February, 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 73-105 is/are pending in the application.
- 4a) Of the above claim(s) 73-82 and 90-105 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 83-85 and 89 is/are rejected.
- 7) ☒ Claim(s) 86-88 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 January, 2004, is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 07/07/04; 12/03/04.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

Serial No.: 10/758,683  
Applicant: Whitcomb, J.

Docket No.: 11068-078-999  
Filing Date: 01/14/2004

### **Detailed Office Action**

#### ***Status of the Claims***

Claims 73-105 are pending in the instant application. Applicant's election of Group III (claims 83-89) without traverse in the communication filed 04 December, 2006, is acknowledged.<sup>1</sup> Because applicant did not distinctly and specifically point out the purported errors in the restriction requirement, the election has been treated as an election without traverse (refer to M.P.E.P. § 818.03(a)). Claims 73-82 and 90-105 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

#### **37 C.F.R. § 1.98**

The information disclosure statements filed 07 July, and 03 December, 2004, have been placed in the application file and the information referred to therein has been considered.

#### **37 C.F.R. § 1.125(a)**

A substitute specification excluding the claims is required pursuant to 37 C.F.R. § 1.125(a) because the specification is illegible in several places and contains various markings that will create complications during the printing process. For example, numerous page numbers are illegible (e.g., see page 2), there are markings throughout the specification (e.g, see page

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<sup>1</sup> Two communications (filed 04 December, 2006, and 05 February, 2007) were received by the Office in response to the restriction requirement mailed 04 October, 2006, electing two different inventions. Applicant's representative contacted the examiner and indicated that applicants wished to rely upon the election set forth in the communication filed 04 December, 2006.

26), and the specification is illegible throughout (e.g., see page 54). A substitute specification must not contain new matter. The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strikethrough except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strikethrough cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown.

Applicants are reminded that the specification (including the abstract and claims), and any amendments for applications, except as provided for in 37 C.F.R. § 1.821 through 1.825, must have text written plainly and legibly either by a typewriter or machine printer in a nonscript type font (e.g., Arial, Times Roman, or Courier, preferably a font size of 12) lettering style having capital letters which should be at least 0.3175 cm. (0.125 inch) high, but may be no smaller than 0.21 cm. (0.08 inch) high (e.g., a font size of 6) in portrait orientation and presented in a form having sufficient clarity and contrast between the paper and the writing thereon to permit the direct reproduction of readily legible copies in any number by use of photographic, electrostatic, photo-offset, and microfilming processes and electronic capture by use of digital imaging and

optical character recognition; and only a single column of text. See 37 C.F.R. § 1.52(a) and (b). The application papers are objected to because [ 1 ]. A legible substitute specification in compliance with 37 C.F.R. § 1.52(a) and (b) and § 1.125 is required.

#### **Abstract**

The abstract of the disclosure is objected to because it fails to describe the salient characteristics of the elected invention. Applicants are reminded that the claims under examination are directed toward an assay assessing the effectiveness of NNRTIs by assessing mutations at amino acids 190, 101, 103, and 98. Applicants should amend the specification to more accurately reflect the claimed invention. See M.P.E.P. § 608.01(b).

#### **35 U.S.C. § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 83-85 and 89 are rejected under 35 U.S.C. § 102(a) as being clearly anticipated by Fujiwara et al. (1998). Fujiwara and colleagues disclose a method for assessing the effectiveness of various NNRTIs on HIV-infected patients. The authors identified (see Table 5, p. 1342) the presence of mutations and codons 190 and 103

(e.g., G190A and K103N) that correlated with the claimed phenotype. Accordingly, this teaching meets all of the claimed limitations.

#### ***Allowable Subject Matter***

Claims 86-88 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. It appears that the combination of mutations G190A/S, K101E, and A98G are free of the prior art. Appropriately drafted claim language directed toward these combinations of mutations would be allowable (e.g., G190A/S and K101E; G190A/S, K101E, and K103N; G190A/S and A98G; etc.).

#### ***Correspondence***

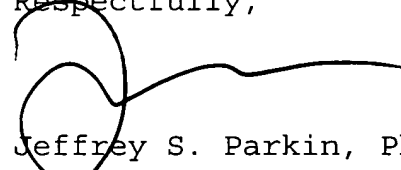
Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the

Updated Notice of Centralized Delivery and Facsimile  
Transmission Policy for Patent Related Correspondence, and  
Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29,  
2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,



Jeffrey S. Parkin, Ph.D.  
Primary Examiner  
Art Unit 1648

05 March, 2007